

**Science Advisory Board (SAB)
Supplemental Guidance for Assessing Cancer Susceptibility (SGACS) Review Panel
Teleconference Meeting
June 20, 2003 – U.S. EPA, Washington, DC**

Panel Members: See Panel Roster (Attachment A)

Date and Time: Friday, June 20, 2003, 3:00 to 5:00 p.m. EDT

Location: U.S. Environmental Protection Agency
Ariel Rios Federal Building, Room 6013
1200 Pennsylvania Avenue NW
Washington, DC 20005

Purpose: The purpose of this public teleconference meeting was to continue the review of the EPA Office of Research and Development (ORD) draft document titled, "Supplemental Guidance for Assessing Cancer Susceptibility From Early-Life Exposure to Carcinogens" (SGACS).

Attendees:

Chair:	Dr. Henry Anderson
SAB Members:	Dr. Ulrike Luderer Dr. Anne Sweeney Dr. Richard Vetter
CHPAC Members:	Dr. Daniel Goldstein
SAP Members:	Dr. Steven Heeringa Dr. Christopher Portier
EPA SAB Staff:	Dr. Suhair Shallal Dr. Vanessa Vu

Other Persons Attending:

Via telephone: EPA personnel and members of the public, as noted on the list of callers (Attachment B).

Meeting Summary

The meeting generally followed the schedule presented in the meeting agenda. (Attachment C)
The meeting adjourned at 4:55 p.m.

Roll Call and Opening

Dr. Suhair Shallal, Designated Federal Officer for SGACS, called the roll of panel members, asked other persons participating via telephone to identify themselves, and welcomed participants to the teleconference.

Welcome and Next Steps

Dr. Anderson expressed his thanks to panel members for their efforts. He noted that changes already suggested for the draft report have clarified the panel's intent, and that today's call was for the panel to word-smith the draft, beginning with the responses to the questions, and ending with the Executive Summary. Dr. Anderson reminded the panel that a final teleconference, for sign-off on the report, will be held Tuesday, August 5, 3:00 to 5:00 p.m. EDT.

Question #1

Discussion on the response to Question #1 began at 3:15 p.m. Dr. Anderson commented that there were not many changes in the draft, and suggested that any minor typographical items be handled off-line. Dr. Goldstein noting that the last paragraph on page 21 was not clear concerning what the panel was recommending the Agency do. The panel concluded that the paragraph should be combined with the first paragraph on page 22 to complete the thought. Dr. Shallal read the written comments of Dr. Marty, who was not able to attend the call; the panel accepted those comments as well.

Question #2

The panel began discussing its response to Question #2 at 3:25 p.m. Clarification to the first sentence in the response was discussed. The panel discussed whether it should comment on the issue of how to use adult MOA data; Dr. Shallal suggested looking at the charge questions. Dr. Anderson commented that if the MOA is known, decisions should be made on a case-by-case basis, including determining if the MOA is relevant to children. Dr. Portier suggested the incorporation of wording from the charge question and addressing the question in two parts for clarity. The panel members concurred that the suggested language was better and resolved any confusion.

Dr. Anderson pointed out that the revised language might need to be included in the paragraph on page 28 that begins "In summary." Dr. Portier agreed, and Dr. Anderson also said that the language needed to be carried forward to the Executive Summary.

Dr. Shallal pointed out a sentence in the summary paragraph about data quality guidelines, which included the phrase “development of a policy.” The panel suggested changing the phrase to “consideration.” Dr. Portier, who had originally suggested the wording, recommended that it be removed.

Question #3

At 3:40 p.m., the panel began its discussion of Question #3. Dr. Goldstein suggested that the last sentence of the response (page 30) was unclear regarding what the panel was asking the Agency to do. Discussion followed regarding the point that the panel was attempting to convey in the paragraph, relating to the use of a factor of 10. The panel concluded that sections of the response could be deleted or revised and shortened. Dr. Shallal read a comment by Dr. Marty; the panel decided that paragraph read clearly without the suggested change.

Question #4

The panel’s review of the response to Question 4 began at 4:02 p.m. Dr. Goldstein pointed out that a paragraph on page 32 also appears on page 35, where it is more appropriate; he suggested deleting the paragraph on page 32. Panel members agreed. Dr. Luderer suggested that the subsequent paragraph on page 32 would then need revision. Comments by Dr. Marty were discussed, and the panel chose to keep the changes initially discussed, noting that they were broader and more reflective of the intent of the response.

Question #5

Discussion of Question #5 commenced at 4:07 p.m. Dr. Goldstein suggested that the recommendation for EPA to improve its statistical analysis needed to be revised, as EPA had not discussed the statistical basis of the values it proposed. Discussion followed about removing the word “statistical.” Dr. Anderson suggested shortening and revising the paragraph.

Dr. Shallal reminded the panel of the issue of data quality. Dr. Anderson pointed out that the panel should say that the decisions need to come out of the science, that policy will be based on the analysis; and that the value of 10 needs to be consistent with the science. Dr. Goldstein said that the panel is asking for both a better statistical analysis and a better explanation of the process by which the Agency arrived at the values of 10 and 3. Dr. Goldstein agreed to provide Dr. Shallal with wording to that effect.

Dr. Shallal directed the panel’s attention to the last paragraph on page 37. Dr. Portier suggested revising the language to say that there was no basis in the analysis; Dr. Heeringa called that suggestion “excellent.” The panel agreed with the paragraph in general. Dr. Goldstein pointed out wording on the same issue on page 38, and suggested that paragraph be moved to where it could work as a summary paragraph, which Dr. Anderson suggested would be just before the response to Question #6.

Dr. Goldstein asked about the use of the word “challenge” at the bottom of page 39. Dr. Portier suggested that it be changed, Dr. Heeringa suggested the word “test,” and Dr. Anderson concurred. The panel also discussed the use of the phrase “adjustment factors,” instead of “policy choices.”

Dr. Portier noted that he could reword the discussion beginning on page 41 to not use formulas, or that the section could be deleted. Panel members concurred that the section should be left unchanged.

Questions #6-8

The panel began discussing the responses to these three questions at 4:34 p.m. Dr. Goldstein proposed a reorganization of the response to Question #6 to better cluster the issues together. The panel accepted the suggestion.

There were no comments on Question #7.

Regarding Question #8, Dr. Goldstein pointed out that the panel might be asking the Agency to do something that is not feasible, in the discussion on page 49 about evaluating chemicals that are structurally similar. Dr. Anderson said that the panel should drop the recommendation that the Agency put this in the SGACS, and should recommend that the Agency consider evaluating the issue. Dr. Goldstein also recommended deleting the last clause in the last sentence on page 51 for clarity.

In response to an inquiry from Dr. Shallal, Dr. Anderson said that the section on “General Comments” should be renamed “Miscellaneous.”

Executive Summary

At 4:45, the panel began discussing the Executive Summary. Dr. Goldstein suggested that the reference to a third age grouping on page 8 be changed to “additional” for clarity; Dr. Anderson concurred. Dr. Goldstein also suggested expanding the answer to Question #5 by adding the first two sentences from the summary response here. Dr. Anderson agreed.

Dr. Luderer asked that the second and third paragraphs on page 2 of the Executive Summary, which summarize the draft SGACS, be set aside by a heading or an indent, so that they are not confused with panel recommendations.

Dr. Goldstein pointed out a typographical error on the title page, where “carcinogenesis” is used instead of “carcinogens.”

The panel discussed a clarification of the language in the summary of Question #6 to more clearly capture its recommendations regarding endocrine disruption and estrogenic agents.

Dr. Sweeney commented that the last sentence of the Executive Summary was unclear; Dr. Anderson said that he would replace it with the language crafted today by Dr. Portier.

Drs. Shallal and Anderson reminded panel members to send in any comments or revisions they have. Dr. Anderson asked the panel to be prepared to give a careful read-through to the next draft, which will be sent out shortly. The report will be finalized at the August 5 teleconference, during which the cover letter will also be discussed.

Dr. Anderson thanked the panel members for their participation. The meeting was adjourned at 4:55 p.m.

Respectfully Submitted:

/Signed/

Dr. Suhair Shallal
Designated Federal Official

Certified as True:

/Signed/

Dr. Henry Anderson, Chair
Supplemental Guidance for Assessing
Cancer Susceptibility (SGACS) Review Panel

ATTACHMENTS

Attachment A	Roster of SGACS Review Panel Members http://www.epa.gov/sab/pdf/sgacsrproster.pdf
Attachment B	List of Callers for June 20, 2003 SGACS Panel Teleconference
Attachment C	Meeting Agenda http://www.epa.gov/sab/03agendas/sgacsa620.pdf
Attachment D	Draft Report, June 20, 2003 http://www.epa.gov/sab/pdf/sgacsdftrpt062003.pdf

ATTACHMENT B

List of callers for June 20, 2003 SGACS panel teleconference

1. Steve Gibb, Risk Policy Report
2. Angelina Duggan, CropLife America
3. Marco Bianci, Michigan DEQ
4. Helen Goeden, Minnesota Dept. of Health
5. Karen Perry, Physicians for Social Responsibility
6. Veronica O'Leary, EPA intern
7. Brian Mayes, General Electric-Center for R&D
8. Bill Wood, EPA Risk Assessment Forum
9. Michael Firestone, EPA Office of Children's Health Protection
10. Margo Schwab, OMB
11. Laura Solem, Minnesota Pollution Control Agency
12. Doland Juberg, DOW Agrochemicals
13. Ed Gray, FQPA Implementation Working Group